



<NOTICE>

<PREAMB>

[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Workshops for the Development of New Antibacterial Products

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice of Public Workshop.

SUMMARY: The National Institutes of Health (NIH), Office of the Director, Office of Science Policy, and the Food and Drug Administration (FDA), Office of the Commissioner, are announcing a public workshop titled “The Development of New Antibacterial Products: Charting a Course for the Future.” The workshop is being held to: (1) examine key issues and challenges related to antibacterial product development, (2) discuss regulatory pathways for bringing new antibacterial drugs to market, (3) identify strategies for promoting clinical trials for antibacterial drugs, and (4) encourage partnerships to accelerate the development of new antibacterial drugs. The workshop is open to the public and is free of charge.

DATES: The workshop will be held on July 30 and 31, 2014, from 8:00 a.m. to 5:15 p.m. and from 8:00 a.m. to 1:00 p.m., respectively. The registration deadline is July 14, 2014.

ADDRESSES: The workshop will be held at the Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Road, North Bethesda, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Kelly Fennington, NIH, Office of Science Policy, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892-7985; 301-496-9838; e-mail: FenningK@mail.nih.gov.

SUPPLEMENTARY INFORMATION: Specific issues to be discussed at this workshop include: (1) priorities and strategic approaches to conducting clinical trials for antibacterial drugs; (2) regulatory pathways, including streamlined programs for the development of antibacterial drugs for patients with limited or no treatment options; (3) clinical trial design, including the development of a common clinical protocol, use of common control groups, statistical design, data sharing across trial, clinical trial endpoints, and lessons learned from other therapeutic areas; and (4) the role of public-private partnerships in advancing the development of antibacterial drugs. Participants will include individuals from the professional and scientific societies, academia, patient communities, pharmaceutical and biotechnology sectors, diagnostic development community,

foundations, NIH, FDA, Biomedical Advanced Research and Development Authority (BARDA), and the general public.

The meeting agenda can be accessed at <http://osp.od.nih.gov/office-biotechnology-activities/event/2014-07-30-120000-2014-07-31-170000/development-new-antibacterial-products-charting-course-future>.

You are encouraged to pre-register for the meeting due to space limitations at <http://palladianpartners.cvent.com/AMRWorkshopJuly2014>, and the deadline for registration is July 14, 2014. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed above in advance of the meeting.

Dated: June 25, 2014.

Lawrence A. Tabak,
Principal Deputy Director,
National Institutes of Health.

<FRDOC> [FR Doc. 2014-15436 Filed 6-30-14; 8:45 am]

<BILCOD>BILLING CODE 4140-01-P

[FR Doc. 2014-15436 Filed 06/30/2014 at 8:45 am; Publication Date: 07/01/2014]